

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK  
WHITE PLAINS DIVISION

----- X  
ALEX HERSHMAN and DORA  
HERSHMAN,

Plaintiffs,

v.

MEDTRONIC, INC.,

Defendant.  
----- X

Civil Action

No. \_\_\_\_\_

08 CIV. 7689

JUDGE SEIBEL

**NOTICE OF REMOVAL**

Defendant Medtronic, Inc. ("Medtronic"), a Minnesota corporation with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota, by and through its undersigned counsel, hereby provides notice pursuant to 28 U.S.C. § 1446 of its removal of the above-captioned case from the State of New York Supreme Court, County of Westchester, to the United States District Court for the Southern District of New York, White Plains Division. The grounds for removal are as follows:

1. Plaintiffs commenced this action by filing a complaint on August 6, 2008 in the State of New York Supreme Court, County of Westchester. A summons was issued on August 6, 2008, and the case was docketed at 08 17085.

2. Copies of the complaint and summons were served upon Medtronic on August 18, 2008. A true and correct copy of the complaint and summons are attached hereto as Exhibit A. No other pleadings or papers have been filed in this litigation.

3. As set forth in more detail below, because Plaintiffs are citizens of New York and Plaintiff's decedent was a citizen of New York and Medtronic is a citizen of Minnesota, and

because the amount in controversy exceeds \$75,000.00 exclusive of interest and costs, this Court has original jurisdiction under 28 U.S.C. § 1332. Accordingly, this case is removable under 28 U.S.C. § 1441.

4. Under 28 U.S.C. § 1446(b), this Notice of Removal must be filed within 30 days of the service upon Medtronic of the complaint and summons. Since Medtronic is filing this Notice on September 2, 2008, removal is timely.

5. The time for Medtronic to answer, move, or otherwise plead with respect to the complaint has not yet expired.

6. Concurrent with the filing of this Notice, Medtronic is serving this Notice on Plaintiffs' counsel and filing a copy of the Notice with the Clerk of the State of New York Supreme Court, County of Westchester. Venue is proper in this Court pursuant to 28 U.S.C. §§ 84(d) and 1441(a), because the United States District Court for the Southern District of New York, White Plains Division, is the federal judicial district and division embracing the State of New York Supreme Court, County of Westchester, where this action was originally filed.

7. By filing a Notice of Removal in this matter, Medtronic does not waive its right to object to service of process, the sufficiency of process, jurisdiction over the person, or venue, and Medtronic specifically reserves the right to assert any defenses and/or objections to which it may be entitled.

#### **Diversity of Citizenship**

8. This Court has original jurisdiction over this action pursuant to 28 U.S.C. § 1332. Diversity jurisdiction exists where (1) the amount in controversy exceeds \$ 75,000, and (2) the suit is between citizens of different states. *Eisenberg v. New Eng. Motor Freight, Inc.*, No. 08 Civ. 01469 (VM) (DF), 2008 U.S. Dist. LEXIS 49749, at \*4 (S.D.N.Y. May 30, 2008).

9. Complete diversity exists between the parties to this action. Medtronic is a Minnesota corporation with its principal place of business in Minnesota, and thus is a citizen of Minnesota. *See* Compl. ¶ 6; *Branson v. Medtronic, Inc.*, No. 5:06-cv-332-Oc-10GRJ, 2007 WL 170094 at \*4 (M.D. Fla. Jan. 18, 2007) (denying plaintiff's motion to remand following removal by Medtronic on the ground that Medtronic's principal place of business is in Minnesota).

10. Upon information and belief, Plaintiffs are citizens and residents of New York. Compl. ¶¶ 1-2.

11. Because the Plaintiffs are citizens of New York and Defendant is a citizen of Minnesota, complete diversity exists in this action.

#### **Amount in Controversy**

12. The amount in controversy requirement of 28 U.S.C. § 1332 is also satisfied. The amount in controversy in a case where federal jurisdiction is based on diversity of citizenship must exceed \$75,000, exclusive of interest and costs. 28 U.S.C. § 1332(a).

13. Here, the allegations in Plaintiffs' complaint demonstrate that they seek damages far in excess of \$75,000, exclusive of interest and costs. As discussed below, Plaintiffs in their Complaint specifically seek recovery of Seventy Million Dollars (\$70,000,000) in compensatory damages, plus punitive damages.

14. Plaintiffs allege that Defendant's product – a defibrillator lead implanted into Plaintiff's decedent's heart – malfunctioned, causing Plaintiffs to "suffer[] severe personal injuries, including, but not limited to, electric shock and extreme chest pain." Compl. ¶ 40. Plaintiffs also allege that "[a]s a direct and proximate result of Defendant's conduct, Plaintiffs suffered severe personal injury, economic loss, pecuniary loss, loss of companionship and society, mental anguish and other compensable injuries." *Id.* at ¶ 47. *Accord id.* at ¶ 56

(“Plaintiffs suffered and will continue to suffer severe personal injury, economic loss, pecuniary loss, loss of companionship and society, mental anguish and other compensable injuries.”). Plaintiffs further allege that “Plaintiffs have suffered profound, permanent injuries; required medical treatment and hospitalization; became liable for medical and hospital expenses; lost financial gain; was kept from ordinary activities and duties and will continue to experience mental suffering; some of which damages will continue in the future.” *Id.* at ¶ 67. *Accord id.* at ¶¶ 77, 89, 100. Moreover, Plaintiff Dora Hershman seeks damages for loss of consortium, including “maintenance, support, service, society and companionship” and alleges that Medtronic is liable for Ms. Hershman’s “necessaries, including medical expenses.” *Id.* at ¶ 104. Finally, plaintiffs seek punitive damages as well. *See id.* at ¶ 105 & pp. 17-18 (prayer for relief).

15. Plaintiffs’ allegations of injury are similar to others that have been found to satisfy the amount-in-controversy requirement. For example, in *Gebbia v. Wal-Mart Stores*, 233 F.3d 880, 888 (5th Cir. 2000), the Fifth Circuit found that alleged damages in a slip and fall case for “medical expenses, physical pain and suffering, mental anguish and suffering, loss of enjoyment of life, loss of wages and earning capacity, and permanent disability and disfigurement” satisfied the jurisdictional amount. *See also Lockett v. Delta Airlines, Inc.*, 171 F.3d 295, 298 (5th Cir. 1999) (finding that damages to property, travel expenses, emergency ambulance trip, 6-day hospitalization, pain and suffering, humiliation, and an inability to do housework satisfied the jurisdictional amount); *Pinson v. Knoll, Inc.*, No. 07 Civ. 1739 (RPP), 2007 U.S. Dist. LEXIS 44201, at \*2-3 (S.D.N.Y. June 18, 2007) (finding that allegations including severe and permanent physical injuries to hand, wrist, foot, and knee, mental suffering, and pain and suffering, in addition to plaintiff’s statement that damages were not expected to exceed \$3,500,000, satisfied the jurisdictional amount).

16. Indeed, in their prayer for relief, Plaintiffs specifically seek "Ten Million Dollars (\$10,000,000.00) on each Cause of Action for a total of Seventy Million Dollars (\$70,000,000.00)" in addition to punitive damages. *Id.* at pp. 17-18. The amount-in-controversy requirement is plainly satisfied where, as here, a plaintiff specifically requests damages in an amount greater than the jurisdictional minimum. *E.g., Boston Post Rd. Med. Imaging, P.C. v. Allstate Ins. Co.*, 221 F.R.D. 410, 411-12 (S.D.N.Y. 2004) (recognizing diversity jurisdiction where plaintiff sought damages of \$102,154.99 plus legal fees).

17. Because both of the requirements for federal diversity jurisdiction are satisfied, this case is removable by Medtronic.

WHEREFORE, Notice is given that this action is removed from the State of New York Supreme Court, County of Westchester, to the United States District Court for the Southern District of New York, White Plains Division.

DATED: September 2, 2008

Respectfully submitted,

MAYER BROWN LLP

By:   
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Mauricio A. España

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*Attorneys for Defendant Medtronic, Inc.*

SUPREME COURT OF THE STATE OF NEW YORK  
COUNTY OF WESTCHESTER

-----X  
ALEX HERSHMAN AND DORA HERSHMAN

Plaintiffs,

-against-

MEDTRONIC, INC.,

Defendants. -----X

Index No.: 17085/08

Date Purchased: 8/6/08

**SUMMONS WITH VERIFIED  
COMPLAINT**

Plaintiffs designate

**WESTCHESTER**

County as the place of trial based  
upon Plaintiffs' residence

**TO THE ABOVE-NAMED DEFENDANTS:**

YOU ARE HEREBY SUMMONED to answer the complaint in this action and to serve a copy of your answer, or, if the complaint is not served with this summons, to serve a notice of appearance, on the Plaintiff's attorneys within twenty (20) days after service of this summons, exclusive of the day of service (or within 30 days after the service is complete if this summons is not personally delivered to you within the State of New York); and in case of your failure to appear or answer, judgment will be taken against you by default for the relief demanded in the complaint.

Dated: New York, New York  
August 1, 2008

NAPOLI BERN RIPKA & ASSOCIATES, LLP  
*Attorneys for Plaintiffs*

  
Christopher R. LoPalo

350 Fifth Avenue, Suite 7413  
New York, New York 10118  
212.267.3700 (phone)  
212.587.0031 (fax)

*Defendants' business addresses:*  
Medtronic, Inc.  
710 Medtronic Parkway  
Minneapolis, MN 55432-5604

*Service Agent:* C.T. Corporation System  
111 Eight Avenue  
New York, NY 10011

SUPREME COURT OF THE STATE OF NEW YORK  
COUNTY OF WESTCHESTER

-----X  
ALEX HERSHMAN AND DORA HERSHMAN

Plaintiffs,

-against-

MEDTRONIC, INC.,

Defendants.  
-----X

Index No.:

Date Purchased: \_\_\_\_\_

**VERIFIED COMPLAINT  
DEMAND FOR JURY TRIAL**

Plaintiffs, by and through their attorneys, **NAPOLI BERN RIPKA & ASSOCIATES  
LLP**, allege upon information and belief, as follows:

**PARTIES**

1. Plaintiff, ALEX HERSHMAN, is a resident of the State of New York and a resident of Westchester County.

2. Plaintiff DORA HERSHMAN, is a resident of the State of New York and a resident of Westchester County.

3. On or about August 8, 2005, Plaintiff ALEX HERSHMAN had a Medtronic Entrust Defibrillator implanted.

4. Plaintiff ALEX HERSHMAN was implanted with a Medtronic Sprint Fidelis Lead, Model # 6949.

5. As a result of the aforementioned implantations, Plaintiff ALEX HERSHMAN was severely injured.

6. Defendant MEDTRONIC, INC. (hereinafter referred to as "Medtronic") is a publicly traded corporation incorporated under the laws of the State of Minnesota having its principal place of business in the state of Minnesota.

7. Medtronic describes itself as a "global leader in medical technology" and as of April 29, 2005 posted \$10.555 billion in revenue. It employs approximately 32,000 employees worldwide.

8. At all times relevant hereto, Defendant Medtronic was and continues to be engaged in the business of testing, developing, manufacturing, distributing, licensing, labeling, selling and marketing, either directly or indirectly through third parties or related entities, implantable cardiac defibrillators ("ICDs") and cardiac resynchronization therapy devices (CRT-Ds"), including the capacitors, leads and batteries required for their operation. Medtronic's Cardiac Rhythm Management (CRM) business "develops products that restore and regulate a patient's heart rhythm, as well as improve the heart's pumping function".

9. At all times relevant hereto, Medtronic transacted business within the State of New York or contracted anywhere to supply goods or services in New York.

10. At all times relevant hereto, Medtronic regularly did and/or transacted and/or solicited business in the State of New York or was engaged in other persistent courses of conduct or derived substantial revenue from goods used or consumed or services rendered in New York.

11. At all times relevant hereto, Medtronic expected or should have reasonably expected its acts to have consequences within the State of New York and it derived and continues to derive substantial revenue from interstate or international commerce.

12. At all times relevant hereto, Medtronic placed the their implantable cardiac defibrillators ("ICDs") and cardiac resynchronization therapy devices (CRT-Ds"), including the capacitors, leads and batteries required for their operation into the stream of commerce and derived substantial benefit from the products which were sold for profit in the State of New York by Medtronic, its agents, servants, associates, subsidiaries and/or employees.



### FACTS

13. On October 15, 2007 Medtronic, Inc. (Medtronic) recalled their Sprint Fidelis Lead Devices (Models: 6930, 6931, 6948, 6949) due to the potential for lead fractures.

14. On information and belief Medtronic was aware prior to October 15, 2007 that their Sprint Fidelis Leads were susceptible to product failure.

15. On the same day that Medtronic suspended sales of their Sprint Fidelis Lead Devices, the FDA issued a statement which stated in part, “[b]ased on our initial review of reported adverse events, some deaths and major complications have occurred after the leads have been fractured.”

16. Medtronic recklessly failed to disclose the potential for fracture in their Sprint Fidelis Leads and continued to sell the Sprint Fidelis Lead Devices with the known defect.

17. The FDA further stated that “no more Sprint Fidelis leads will be sold or manufactured and any remaining product should be pulled from inventory and returned to the company.”

18. Medtronic sold the Sprint Fidelis Lead Devices to hospitals and physicians for implantation into patients who have had or are at risk for having life-threatening ventricular arrhythmias, an electrophysiological change in the heart’s rhythm resulting in a change in heart rhythm. Uncorrected cardiac arrhythmia can lead to ventricular fibrillation (“v-fib”), which is lethal unless the individual receives an electric shock from an appropriate device. Such device can “throw” the heart out of v-fib and into normal cardiac rhythm also known as “sinus rhythm.”

19. The Medtronic Sprint Fidelis Lead Devices deliver electrical jolts to the heart from a defibrillator implanted in a patient’s chest.

20. The defibrillator device is surgically implanted under the left pectoralis muscle. Wires, called leads, are then inserted through a blood vessel and attached to the heart. It is via these

leads that any irregularity in the heart's rhythm is detected and a corrective shock, as needed, is delivered.

21. A person with cardiovascular disease requires an implantable cardiac defibrillator ("ICD") as a monitor and response mechanism when the heart develops a chaotic or irregular rhythm.

22. ICD's monitor, regulate and stabilize the heart in the event of an increase or decrease in heart rhythm.

23. ICD's monitor, regulate and stabilize the heart in the event of an increase or decrease in heart rhythm or sudden heart failure.

24. If a cardiac disturbance occurs, the function of the ICD is to deliver an electric shock to the heart rhythm or sudden heart failure.

25. If a cardiac disturbance occurs, the function of the ICD is to deliver an electric shock to the heart to restore the heart to sinus rhythm.

26. The ICD is implanted in a pouch formed in the chest wall and connected directly to the heart muscle via an insulated lead wire.

27. Electrodes that sense the heart's rhythm are placed in the heart.

28. Electric currents are sent from the ICD through the insulated leads to the heart, which is shocked back into a steady rhythm. Patients who suffer from abnormally fast heart rhythm (tachycardia) rapid, ineffective contraction of the ventricles of the heart (ventricular fibrillation) or significant thickening of the heart muscle are also treated with ICDs to regulate heart rhythms.

29. Without the aid of an ICD, the conditions set forth above the arrhythmias can lead to cardiac arrest or sudden death.

30. The recall affects approximately 268,000 Sprint Fidelis Lead Devices that have been implanted worldwide.

31. If the Medtronic Sprint Fidelis Lead Device operates properly, it will save the life of the person in whom it was implanted. If the lead does fracture it could cause the defibrillator to deliver unnecessary shocks or to not operate at all. If it fails to operate when needed, the patient will likely die unless paramedic reach the person in less than 7 to 8 minutes.

32. Medtronic's Sprint Fidelis Lead Devices are uniformly defective in that they are susceptible to fracture.

33. Patients' surgical implanted leads have to closely examined and monitored to determine whether they have fractured since there seems to be no other way to ascertain whether a fracture has occurred.

34. Since the Medtronic Sprint Fidelis Lead Devices are implanted in the chest with lead wire linked directly to the heart, there are risks and complications associates with any surgeries required for the examination and/or replacement of the leads.

35. Defendants knew or had reason to know, of the defect in the Medtronic Sprint Fidelis Lead Devices. This knowledge was concealed from Plaintiffs, the medical community, and the public at large.

36. Defendant's dangerous and careless conduct of concealment, equate to conduct purposely committed, without regard for the rights and safety of the Plaintiffs.

37. On or about August 8, 2005 Plaintiff ALEX HERSHMAN had implanted a Medtronic Entrust Defibrillator (hereinafter, "defibrillator", or "ICD"), model number D154AT, serial number PNR 400947.

38. On or about August 8, 2005 Plaintiff ALEX HERSHMAN, had implanted a SPRINT FIDELIS lead (hereinafter, "lead"), serial/model number LFJ078700V/694965ID.

39. On or about January 11, 2007, Plaintiff ALEX HERSHMAN, had implanted a SPRINT FIDELIS lead (hereinafter, "lead"), serial/model number LFJ199635V/6949

40. As a result of the implanted ICD and Sprint Fidelis leads the Plaintiffs suffered severe personal injuries, including, but not limited to, electric shock and extreme chest pain.

**AS AND FOR A FIRST CAUSE OF ACTION:  
NEGLIGENCE**

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41. Plaintiffs repeat, reiterate, and reallege each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

42. Defendant carelessly and negligently manufactured, marketed, distributed and sold the aforementioned defective devices.

43. Medtronic was negligent in manufacturing the aforementioned defibrillators and leads, because:

- a. The manufacturing process for the defibrillators, leads and certain of their components did not satisfy the Food and Drug Administration's Pre-Market Approval standards for the devices;
- b. The failure of the manufacturing processes for the defibrillators, leads and certain of their components to satisfy the Food and Drug Administration's Pre-Market Approval standards for the devices resulted in unreasonably dangerous manufacturing defects, and
- c. The Defendant failed to warn of the unreasonable risks created by these manufacturing defects.

44. Although the Food and Drug Administration's Pre-Marketing Approval process imposed requirements on the Defendants in connection with the manufacture and marketing of Medtronic defibrillators and leads, it did not impose specific health or safety requirements on the device itself.

45. Defendants concealed the defects in its products from the FDA, from physicians, and from the patients who were to receive the devices.

46. Replacement of the defective devices requires surgery that can result in complications that may cause damage to the patient's heart and other injuries to the patient.

47. As a direct and proximate result of Defendant's conduct, Plaintiffs suffered severe personal injury, economic loss, pecuniary loss, loss of companionship and society, mental anguish and other compensable injuries.

48. By reason of the foregoing, Plaintiffs were damaged by the negligence, wanton and willful recklessness of the Defendants in an amount that exceeds the jurisdictional limits of all lower courts that would otherwise have jurisdiction over this matter.

49. By reason of the foregoing plaintiffs have suffered damages that exceed the jurisdiction of all lower courts.

**AS AND FOR A SECOND CAUSE OF ACTION: STRICT  
PRODUCTS LIABILITY - DEFECTIVE DESIGN**

50. Plaintiffs repeat, reiterate and reallege each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

51. At all times material hereto, Defendants manufactured, marketed, distributed and sold the listed devices in a condition which rendered them unreasonably dangerous due to their propensity to fail without warning.

52. The aforementioned defibrillators and leads manufactured by Medtronic were unreasonably dangerous, because:

- a. The manufacturing process for the defibrillators, leads and certain of their components did not satisfy the Food and Drug Administration's Pre-Market Approval standards for the devices;

- b. The failure of the manufacturing process for the defibrillators, leads and certain of their components to satisfy the Food and Drug Administration's Pre Market Approval standards for the devices resulted in unreasonably dangerous manufacturing defects.
- c. The Defendants failed to warn of the unreasonable risks created by these manufacturing defects.

53. Although the Food and Drug Administration's Pre-Market Approval process imposed requirements on the Defendants in connection with the manufacture and marketing of the ICDs at issue here, it did not impose specific health or safety requirements on the devices themselves.

54. The defects existed when Defendants placed these devices into the stream of commerce.

55. Defendant concealed the defects from the FDA, from physicians, and from the patients who were to receive the devices.

56. As a direct and proximate result of Defendant's conduct, Plaintiffs suffered and will continue to suffer severe personal injury, economic loss, pecuniary loss, loss of companionship and society, mental anguish and other compensable injuries.

57. By reason of the foregoing, Plaintiffs were damaged by the wanton and willful recklessness of the Defendants who will be liable to Plaintiffs in an amount that exceeds the jurisdictional limits of all lower courts that would otherwise have jurisdiction over this matter.

58. By reason of the foregoing Plaintiffs have suffered damages that exceed the jurisdiction of all lower courts.

**AS AND FOR A THIRD CAUSE OF ACTION: STRICT  
PRODUCT LIABILITY - FAILURE TO WARN**

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59. Plaintiffs repeat, reiterate and reallege each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

60. Defendant developed, manufactured, marketed, and distributed the ICD and lead to the general public even after learning of design defects that threatened the intended use of the device.

61. The ICD models and leads with design and/or manufacturing defects were expected to and did reach Plaintiff Alex Hershman without substantial change or adjustment to its mechanical function upon implanting the device.

62. Defendant knew or should have known through testing, adverse event reporting, or otherwise, that the product created a high risk of bodily injury and serious harm.

63. Defendant failed in providing timely and adequate warnings or instruction regarding its device with a known design and/or manufacturing defect.

64. Plaintiffs did not have the same knowledge as Defendant and no adequate warnings were communicated to Plaintiffs.

65. Defendant had a continuing duty to warn the medical community as well as users of their aforementioned defibrillators and leads, including Plaintiffs, of the dangers associated with the aforementioned defibrillators and leads by negligently and/or wantonly failing to adequately warn of the dangers of the use of the aforementioned defibrillators and leads Defendant breached their duty.

66. Defendant's ICDs and leads is a product inherently dangerous for its intended use due to design and/or manufacturing defect and improper functioning. Defendant therefore is strictly liable to Plaintiffs for damages specified herein.

67. As a direct and proximate result of Defendant's failure to warn of the defective and unreasonably dangerous condition of their defibrillators and leads Plaintiffs have suffered profound, permanent injuries; required medical treatment and hospitalization; became liable for medical and

hospital expenses; lost financial gain; was kept from ordinary activities and duties and will continue to experience mental suffering; some of which damages will continue in the future.

68. By reason of the foregoing, Plaintiffs were damaged by the wanton and willful recklessness of the Defendant who will be liable to Plaintiffs in an amount that exceeds the jurisdictional limits of all lower courts that would otherwise have jurisdiction over this matter.

69. By reason of the foregoing plaintiff has suffered damages that exceed the jurisdiction of all lower courts.

**AS AND FOR A FOURTH CAUSE OF ACTION: BREACH  
OF IMPLIED WARRANTY OF MERCHANTABILITY**

70. Plaintiffs repeat, reiterates and reallege each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

71. Defendant is a "merchant" as defined in *N.Y. UCC* § 2-104.

72. Defendant's aforementioned ICD and lead device is a "good" as defined in *N.Y. UCC* § 2-105.

73. At the time Defendant designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packages, supplied and/or distributed their ICD device, Defendant knew of the use for which the ICD device was intended and impliedly warranted the ICD to be of merchantable quality and safe and fit for its intended use.

74. Plaintiff Alex Hershman, in using Defendant's ICD device and lead, reasonably relied upon the skill and judgment of Defendant as to whether their ICD device and lead were of merchantable quality and safe and fit for its intended, reasonably foreseeable and/or ordinary use.



75. In breach of the implied warranty given by Defendant, Defendant's ICD device and lead were not of merchantable quality or safe or fit for its intended, reasonably foreseeable and/or ordinary use because the products were and are unreasonably dangerous and unfit for the intended, reasonably foreseeable and/or ordinary purpose for which it was to be used, as described above.

76. In breach of the implied warranty given by Defendant, Defendant's ICD device and lead were not of merchantable quality or safe or fit for their intended, reasonably foreseeable and/or ordinary use because, among other things:

- a. Use of Defendant's ICD device and lead carried a risk of, among other things, serious electric shock, extreme chest pain and death;
- b. Defendant failed to include adequate warnings with their ICD device and lead that would alert the medical and/or scientific communities and users of their ICD device and lead, including the Plaintiffs, of the potential risks and serious side effects of their ICD device;
- c. Defendant failed to provide adequate post-marketing warnings and/or instructions after Defendant knew or should have known of the risks and serious side effects posed by the use of their ICD device and lead.

77. As a direct and proximate result of Defendant's breach of warranty, Plaintiffs suffered profound, permanent injuries; required medical treatment and hospitalization; was kept from ordinary activities and duties and will continue to experience mental suffering; Plaintiffs became liable for medical and hospital expenses; lost financial gain; some of which damages will continue in the future.

78. By reason of the foregoing, Plaintiffs were damaged by the wanton and willful recklessness of the Defendant who will be liable to the Plaintiffs in an amount that exceeds the jurisdictional limits of all lower courts that would otherwise have jurisdiction over this matter.

79. By reason of the foregoing plaintiffs has suffered damages that exceed the jurisdiction of all lower courts.

**AS AND FOR A FIFTH CAUSE OF ACTION: FRAUD**

80. Plaintiffs repeat, reiterate and reallege each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

81. Defendant recklessly, knowingly, intentionally and fraudulently misrepresented to the medical and/or scientific communities, and users of their ICD device and lead, including the Plaintiff Alex Hershman and his physician(s), the safety and efficacy of their ICD device and lead and/or recklessly, knowingly, intentionally and fraudulently concealed from the medical and/or scientific communities, and users, including the Plaintiffs, material adverse information regarding the safety and efficacy of their ICD device and lead.

82. Defendant's misrepresentations were communicated to the medical and/or scientific communities, and users of their ICD device and lead, including Plaintiff Alex Hershman and his physician(s), with the intent that they reach users of their ICD device and lead, including Plaintiff Alex Hershman.

83. Defendant knew or should have known that the representations were false.

84. Defendant made the misrepresentations and/or actively concealed information concerning the safety and efficacy of their ICD device and lead with the intention and specific desire that the medical community would rely on such in selecting their ICD device and lead for use.

85. Defendant made these misrepresentations and/or actively concealed information concerning the safety and efficacy of their ICD device and lead in its labeling, advertising, product inserts, promotional materials or other marketing efforts.

86. Defendant made these misrepresentations and/or actively concealed adverse information at a time when Defendant knew or should have known that its ICD device and lead had defects, dangers and characteristics that were other than what Defendants had represented to the

medical and/or scientific communities, and users of their ICD device and lead, including the Plaintiff Alex Hershman and his physician(s), such as:

- a. There had been insufficient studies regarding the safety and efficacy of their ICD device and lead;
- b. Defendant's ICD device and lead were fully and adequately tested, despite knowing that there had been insufficient or inadequate testing of the drug;
- c. Prior studies, research, reports and/or testing had been conducted linking the use of their ICD device and lead to serious reactions including, but not limited to the increased risk of severe electric shock, severe chest pain and death;
- d. Defendant knew or should have known of reports of an increased risk of serious electric shock, severe chest pain and death associated with the use of their ICD device and lead, and, despite this information, downplayed the risks of their ICD device and lead.

87. Through Defendant's product inserts, Defendant continued to misrepresent the potential risks and serious side effects associated with the use of Their ICD device and lead; Defendants had a post-sale duty to warn the medical and/or scientific communities, and users of their ICD device and lead including the Plaintiff Alex Hershman and his physician(s), about the potential risks and serious side effects associated with the use of their ICD device and lead in a timely manner yet they failed to provide such warning.

88. The Plaintiffs justifiably relied on and/or was induced by the representations and/or active concealment of Defendant to purchase and use their ICD device and lead to the Plaintiffs' detriment.

89. As a direct and proximate result of the misrepresentations of Defendant, Plaintiffs' suffered profound, permanent injuries; required medical treatment and hospitalization; was kept from ordinary activities and duties; Plaintiffs became liable for medical and hospital expenses; lost financial gain; and Plaintiffs will continue to experience mental suffering; some of which damages will continue in the future.

90. By reason of the foregoing, Plaintiffs were damaged by the wanton and willful recklessness of the Defendant who will be liable to the Plaintiffs in an amount that exceeds the jurisdictional limits of all lower courts that would otherwise have jurisdiction over this matter.

91. By reason of the foregoing Plaintiffs have suffered damages that exceed the jurisdiction of all lower courts.

**AS AND FOR A SIXTH CAUSE OF ACTION: NEGLIGENT  
MISREPRESENTATION**

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92. Plaintiffs repeat and reallege each and every allegation contained in the Complaint as if fully set forth herein.

93. Defendant negligently misrepresented or failed to exercise reasonable care in representing to the medical and/or scientific communities, and users of their ICD device and lead including the Plaintiff Alex Hershman and his physician(s), the safety and efficacy of their ICD device and lead and/or negligently concealed or failed to exercise reasonable care by concealing and failing to disclose to the medical and/or scientific communities, and users of their ICD device and lead, including the Plaintiff Alex Hershman and his physician(s), adverse information regarding the safety and efficacy of their ICD device.

94. Defendant made these representations and/or actively concealed information concerning the safety and efficacy of their ICD device and lead in its labeling, advertising, product inserts, promotional materials and/or other marketing efforts.

95. Defendant either knew or should have known that the representations were false.

96. Defendant knew or should have known that the representations and/or omissions concerning the safety and efficacy of their ICD device and lead would be relied on by the medical and/or scientific communities in selecting their ICD device and lead for use.

97. Defendant made these representations and actively concealed adverse information at a time when Defendant knew or should have known that its ICD device and lead had defects, dangers and characteristics that were other than what Defendant had represented to the medical and/or scientific communities.

98. Specifically, Defendant misrepresented to and/or actively concealed from the medical and/or scientific communities, and users of their ICD device and lead, including the Plaintiff Alex Hershman and his physician(s), that:

- a. There had been insufficient studies regarding the safety and efficacy of their ICD device and lead;
- b. Defendant's ICD device and lead were fully and adequately tested, despite knowing that there had been insufficient or inadequate testing of their ICD device;
- c. Prior studies, research, reports and/or testing had been conducted linking the use of Defendant's ICD device and lead to serious reactions including, but not limited to the increased risk of electrical shock, extreme chest pain and death;
- d. Defendant knew or should have known of reports of the increased risk of electrical shock, extreme chest pain and death;
- e. Defendant knew or should have known of the greatly increased risk of the increased risk of electrical shock, extreme chest pain and death associated with their ICD device and lead and despite this information, downplayed the risks of their ICD device and lead.

99. The misrepresentations of and/or active concealment by Defendant was perpetuated directly and/or indirectly by Defendant, its sales representatives, employees, distributors, agents and/or detail persons.

100. As a direct and proximate result of the misrepresentations of the Defendant, Plaintiffs suffered profound, permanent injuries; required medical treatment and hospitalization; was kept from ordinary activities and duties; and Plaintiffs became liable for medical and hospital expenses; lost financial gain; and Plaintiffs will continue to experience mental suffering; some of which damages will continue in the future.

101. By reason of the foregoing, Plaintiffs were damaged by the wanton and willful recklessness of the Defendant who will be liable to the Plaintiffs in an amount that exceeds the jurisdictional limits of all lower courts that would otherwise have jurisdiction over this matter.

102. By reason of the foregoing plaintiff has suffered damages that exceed the jurisdiction of all lower courts.

**AS AND FOR AN SEVENTH CAUSE OF ACTION: LOSS  
OF CONSORTIUM**

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103. Plaintiffs repeats and realleges each and every allegation contained in the Complaint as if fully set forth herein.

104. Plaintiff DORA HERSHMAN is the spouse of the Plaintiff ALEX HERSHMAN, and as such, seeks to recover a sum of money that would fairly and reasonably compensate her for consortium losses as a result of the injuries of her husband, including the following elements: maintenance, support, service, society and companionship and is liable for her necessities, including medical expenses.

105. By reason of the foregoing, Plaintiff DORA HERSHMAN, the spouse of ALEX HERSHMAN has lost the consortium, services, society and companionship of her husband and has incurred medical expenses on his behalf, and seeks to recover actual damages, compensatory damages, punitive damages, pre and post-judgment interest and all other relief, in law and in equity, to which Plaintiffs may be entitled.

106. By reason of the foregoing Plaintiffs have suffered damages that exceed the jurisdiction of all lower courts.

WHEREFORE, Plaintiffs demands judgment against Defendant jointly and severally, for compensatory damages as well as interest, the costs and disbursements of this action and such other, further and different relief as the Court deems just and proper. Plaintiffs further demands

punitive damages in such an amount as a jury deems reasonable given that Defendant engaged in egregious, tortious conduct by which the Plaintiffs were aggrieved and given that Defendant's egregious, tortious conduct was part of a pattern of similar conduct directed at the public generally.

WHEREFORE, Plaintiffs prays for relief as follows: Ten Million Dollars (\$10,000,000.00) on each Cause of Action for a total of Eighty Million Dollars (\$70,000,000.00):

FIRST CAUSE OF ACTION: NEGLIGENCE  
(\$10,000,000.00)

SECOND CAUSE OF ACTION: STRICT PRODUCTS LIABILITY DEFECTIVE DESIGN  
(\$10,000,000.00)

THIRD CAUSE OF ACTION: STRICT PRODCUTS LIABILITY FAILURE TO WARN  
(\$10,000,000.00)

FOURTH CAUSE OF ACTION: BREACH OF WARRANTY OF MERCHANTABILITY  
(\$10,000,000.00)

FIFTH CAUSE OF ACTION: FRAUD  
(\$10,000,000.00)

SIXTH CAUSE OF ACTION: NEGLIGENT MISREPRESENTATION  
(\$10,000,000.00)

SEVENTH CAUSE OF ACTION: LOSS OF CONSORTIUM  
(\$10,000,000.00)

Plaintiffs further demand trial by jury on all issues to be tried.

Dated: New York, New York  
August 1, 2008

Yours, etc.,



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